UNITED STATES DEPARTMENT OF AGRICULTURE

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THE UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SECTION

> Training Rooms 1 and 2 Second Floor U.S. Department of Agriculture 4700 River Road Riverdale, Maryland 20737

Thursday, March 8, 2001

The hearing in the above-entitled matter was convened, pursuant to notice, at 10:02 a.m.

APPEARANCES:

USDA Panel:

ANISSA CRAGHEAD, Moderator

DR. CATHLEEN ENRIGHT
Director, Biotechnology, APHIS/PPQ/PIM

NARCY KLAG

Director, International Standards Management APHIS/PPQ/PIM

JOHN GREIFER

Director, Trade Support Team, APHIS

Speakers:

BETH BURROWS Edmonds Institute

KIRK MILLER

North American Export Grain Association

APPEARANCES (CONTINUED):

Speakers (Continued):

KELLY REID Greenpeace

JANE RISSLER Union of Concerned Scientists

Also Appearing:

DR. PAUL PFEIFFER State Department Bureau of Oceans, Environment and Science

MARK POWELL USDA, Office of Chief Economists/Office of Risk Assessment and Cost Benefit Analysis

1 PROCEEDINGS 2 (10:02 a.m.) 3 MS. CRAGHEAD: Good morning, everyone. Welcome to 4 the Animal and Plant Health Inspection's public meeting to 5 discuss the recommendation for the development of two separate standards, one for living, genetically-modified 6 7 organisms and another for invasive species under the International Plant Protection Convention. 8 9 International Plant Protection Convention, which I will 10 refer to as IPPC, is recognized as the international standards-setting body for phyto-sanitary standards by the 11 12 World Trade Organization agreement on the application of 13 sanitary and phyto-sanitary measures. My name is Anissa Craghead. And I have been asked 14 15 by the Deputy Administrator for Plant Protection and Quarantine to be the moderator for today's meeting. 16 17 panelists for today's meeting starting on my left are Dr. 18 Cathy Enright, Director of Biotechnology Issues and Phyto-19 sanitary Issues Management, Plant Protection and Quarantine. 20 Cathy is the person responsible for coordinating the Federal 21 Government process for addressing living, genetically-22 modified organisms and invasive species under IPPC. 23 Joining Cathy are Mr. John Greifer, Director of 24 APHIS's Trade Support Team and Mr. Narcy Klag, Program Director for International Standards Development and issues 25

- 1 under the North American Plant Protection Organization.
- 2 John and Narcy coordinate the development of U.S. Government
- 3 positions for a range of IPPC issues and are here to answer
- 4 questions related to IPPC in general.
- 5 The purpose of today's meeting is to provide you
- 6 with background on the issues of living genetically-modified
- 7 organisms and invasive species as they pertain to the IPPC
- 8 and to give interested persons an opportunity to present
- 9 their views on the recommendation for the development of two
- 10 separate IPPC standards: One for living, genetically-
- 11 modified organisms and another for invasive species.
- Notice of today's meeting was published in the
- 13 Federal Register on February 20th, 2001. Extra copies of
- 14 the notice are at the registration table which is right over
- 15 there in the corner. The format for today's meeting will be
- 16 as follows: After I complete my remarks on the procedural
- 17 aspects of the meeting, Dr. Enright will provide you with
- 18 background information of issues of living, genetically-
- 19 modified organisms and invasive species under the IPPC.
- 20 After Dr. Enright's presentation, persons who have
- 21 registered to speak will be given an opportunity to speak in
- 22 the order that they registered. After each speaker
- 23 completes his or her remarks, panelists will have the
- 24 opportunity to provide clarification or additional
- 25 background information if needed and if appropriate to the

- 1 topic of this meeting.
- 2 If time permits, persons who have not registered
- 3 will be given an opportunity to speak, as well, once all
- 4 registered persons have been heard. Today's meeting is
- 5 scheduled to end at 11:30 a.m. Should registered speakers'
- 6 presentations take us over the 11:30 conclusion time, we
- 7 will remain longer to accommodate their presentations.
- 8 Alternately, we may conclude before 11:30 a.m. if
- 9 all persons who have registered to speak have been heard and
- 10 there are no other persons who wish to speak. Seven people
- 11 have registered to speak at today's meeting. Therefore, I
- 12 ask that registered speakers please limit their time to
- around five minutes for their presentations.
- 14 All comments made here today are being recorded
- 15 and will be transcribed. The Court Reporter for today is
- 16 Ms. Marcia Logan who is associated with the Heritage
- 17 Reporting Corporation in Washington, D.C. Detailed
- 18 information on obtaining a copy of the transcript for
- 19 today's meeting is available at the registration table.
- 20 As the moderator, I will call each person who has
- 21 registered to speak. When you are called, please come up to
- the table and sit here and give your remarks into the mike
- 23 so that Marcia can hear them. Before beginning, please
- 24 state and spell your last name for the benefit of the Court
- 25 Reporter. In addition, please say who you represent.

1	If you read a prepared statement and have an extra
2	copy with you, I would appreciate it if you would give me
3	that extra copy at either the beginning or the end of your
4	presentation. Any oral statement presented or written
5	statement submitted at today's meeting will become part of
6	the public record.
7	If an individual's comments do not relate to the
8	stated purpose of today's meeting which is to present
9	comments or questions on the recommendation for IPPC
LO	standards for living, genetically-modified organisms and
L1	invasive species, I will ask the speaker to focus his or her
L2	comments accordingly. In addition, I hope that everyone
L3	will show respect to speakers and give speakers your full
L4	attention.
L5	Finally, I ask that before you leave today, please
L6	take a minute to complete a brief survey concerning the
L7	quality of this meeting. We need your feedback on things
L8	such as the format for the meeting, the accommodations and
L9	the other aspects of the meeting so that we can determine if
20	the way we conducted this meeting has been satisfactory to
21	you.
22	Copies of the survey are available at the
23	registration table. If you don't have time to fill out the
24	survey this morning, please take a copy of it with you and
25	fax it to me when you get a chance. My fax number is on the

- 1 survey. Otherwise, we would really appreciate it if you
- 2 could take a minute to fill it out this morning and then
- 3 just leave your completed survey on the registration table
- 4 and we will pick them up at the end.
- 5 After Dr. Enright's presentation, I will call the
- 6 first registered speaker. Cathy.
- 7 DR. ENRIGHT: Thanks, Anissa. Last June, an IPPC
- 8 working group was convened to consider how best to address
- 9 IPPC responsibility regarding the plant pest concerns
- 10 associated with LMOs and invasive species. The working
- 11 group focused on four areas: The clarification of the role
- of the IPPC, the need for standards, capacity-building, and
- 13 IPPC communication with the convention of biological
- 14 diversity, or the CBD.
- 15 Today after providing an introduction, I will
- 16 touch upon each of these areas, but focus primarily on the
- working group's views on the role of the IPPC and its
- 18 recommendations for the development of two standards, one to
- 19 address the plant pest risks associated with LMOs and one to
- 20 address the environmental impacts of quarantine pests
- 21 including quarantine pests that are invasive. I will then
- 22 describe our views and next steps.
- 23 By way of introduction, the IPPC working group was
- 24 established in response to requests made by a number of IPPC
- 25 members at their October 1999 meeting. The requests were

- 1 for further guidance on addressing plant pest concerns
- 2 associated with LMOs and invasive species. As you may know,
- 3 the IPPC which came into force in 1952 and which the U.S.
- 4 joined in 1972 is aimed at protecting plant health by
- 5 promoting international cooperation to prevent the spread
- 6 and introduction of plant pests and to promote appropriate
- 7 measures for their control.
- 8 The member country focus on LMOs and invasive
- 9 species stemmed largely from heightened global interest in
- 10 these two areas. You will recall in October of 1999, the
- 11 CBDs Cartagena protocol on biosafety was under negotiation.
- 12 The Global Invasive Species Program or GISP, was developing
- its global plan of action. And the Convention on Biological
- 14 Diversity had identified invasive species as a priority in
- 15 its work plan.
- 16 IPPC member countries saw the need to clarify the
- 17 role of the IPPC with regard to LMOs and with regard to
- 18 invasive species. In addition, while several members have
- 19 considerable experience in addressing LMOs and invasive
- 20 species, many members felt ill-equipped to address these
- 21 issues.
- As reflected in its report, the June 2000 working
- 23 group agreed on the need for further guidance under the IPPC
- on LMOs and on invasive species. With regard to LMOs, the
- working group first clarified the role of the IPPC by noting

- 1 that plant pest risks associated with LMOs fall within the
- 2 scope of the IPPC consistent with the IPPC mandate to
- 3 protect plant health.
- 4 The working group also agreed that plant pest risk
- 5 analysis and management systems established under the IPPC
- 6 are certainly appropriate for assessing and managing plant
- 7 pest risks that may be presented by LMOs. Finally, the
- 8 working group recommended the development of a standard to
- 9 specifically address those plant pest risks associated with
- 10 LMOs that are not adequately addressed within existing IPPC
- 11 risk analysis standards.
- 12 With regard to the issue of invasive species, the
- working group clarified the relationship between invasive
- 14 species and quarantine plant pests which are defined and
- 15 regulated under the IPPC. The working group determined that
- 16 a species with the potential to become invasive should be
- 17 considered a quarantine pest if it may directly or
- 18 indirectly affect plant health and if it is absent from the
- 19 region in question or, if present, it is limited in
- 20 distribution and is subject to official control.
- 21 The working group also made clear that as
- 22 quarantined pests, such invasive species would be subject to
- 23 measures according to IPPC provisions and standards.
- 24 Finally, on the issue of quarantined pests generally and
- 25 invasive species specifically, the working group identified

- 1 the need for a standard to address the environmental impacts
- 2 of quarantined pests including quarantined pests that are
- 3 invasive.
- 4 The environmental focus stems from a lack of
- 5 clarity outside the IPPC regarding its responsibility to
- 6 address environmental impacts and a lack of capacity within
- 7 the IPPC to respond and address environmental impacts --
- 8 respond to and address environmental impacts. Within the
- 9 IPPC, the understanding of plant protection has been and
- 10 continues to be broad, encompassing the protection of both
- 11 cultivated and non-cultivated plants and natural flora from
- 12 direct and indirect injury by plant pests.
- 13 Historically, however, the primary application of
- 14 phyto-sanitary measures under the IPPC has been the
- identification, assessment and management of plant pests in
- 16 cultivated settings such as agriculture, horticulture and
- forestry, largely for the assessment of economic
- 18 consequences.
- 19 The result which is not new to discussions within
- 20 the IPPC has been confusion as to the responsibility of the
- 21 IPPC with regard to the protection of natural ecosystems.
- 22 In addition, guidance specific to the environment in current
- 23 or draft IPPC standards is extremely limited. And member
- 24 countries are simply seeking more explicit systems for the
- 25 assessment of environment consequences presented, for

- 1 example, by quarantined pests including those that are
- 2 invasive.
- 3 On the issue of capacity-building, the working
- 4 group identified the need for capacity-building,
- 5 particularly in developing countries and recommended the
- 6 development of a program to specifically address plant pest
- 7 risk assessment and management needs.
- 8 With regard to communication with the CBD, the
- 9 working group acknowledged the importance of such
- 10 communication and has initiated -- has now initiated a
- 11 dialogue with the CBD to ensure that as each organization
- 12 proceeds to address LMOs and to address invasive species,
- 13 the areas of common interest are adequately covered.
- 14 As an aside and an update, with regard to LMOs,
- the CBD's Cartagena protocol on biosafety has been completed
- 16 and has entered the implementation phase. With regard to
- invasive species, the CBD has drafted interim guiding
- 18 principles for combatting invasive species and, working with
- 19 GISP, will begin to develop a work plan in March.
- In terms of U.S. Government views on the working
- 21 group report, we agree with the recommendations. The
- 22 development of an LMO standard and an environmental impact
- 23 standard for quarantined pests will help to address the
- 24 expressed needs of IPPC member countries and will certainly
- 25 help to clarify the responsibility of the IPPC in these

- 1 areas.
- 2 The IPPC's strength in responding to contemporary
- 3 phyto-sanitary issues such as LMOs and invasive species is
- 4 in its development of concrete, regulatory procedures and
- 5 standards. As a result, the recommended standards and
- 6 associated capacity-building programs will help countries
- 7 make better informed phyto-sanitary decisions and will help
- 8 promote a common approach to the identification, assessment
- 9 and control of plant pest risks associated with LMOs and
- 10 with quarantined pests including invasive species.
- 11 These standards will also lead to greater
- 12 transparency within the IPPC regarding the application of
- 13 procedures for identifying any potential plant pest risks
- 14 and the measures taken to control them.
- 15 Regarding next steps, the adoption of the working
- 16 group's report is just one of the items on the agenda for
- 17 the April IPPC meeting. If adopted, the activities outlined
- in the report will be prioritized in the IPPC 2001-2002 work
- 19 plan. Depending on the ranking, working groups for the
- development of the two standards could be convened in late
- 21 summer or early fall this year.
- 22 We have begun to address these issues at the
- 23 regional level with Canada and Mexico under the North
- 24 American Plant Protection Organization, or NAPPO. Our
- 25 intention is to complete an internal review of each of these

- draft efforts and then to begin an iterative process with
- 2 the public to give those interested an opportunity to
- 3 comment on their content.
- 4 The process of standards development under the
- 5 IPPC is years long. Therefore, we envision several
- 6 opportunities beginning with today's meeting for public
- 7 comment. Your comments will help us to prepare for the
- 8 April meeting of the IPPC, will help us to gauge your
- 9 interest in these issues and help us to -- and help to
- 10 inform our approach to standards development. Anissa, I
- 11 will stop there.
- 12 MS. CRAGHEAD: Great. The first registered
- 13 speaker is Ms. Beth Burrows.
- 14 MS. BURROWS: Before Ms. Beth Burrows speaks, she
- 15 wonders if she could ask any questions that were on the
- 16 previous presentation.
- MS. CRAGHEAD: Sure.
- MS. BURROWS: In several places --
- DR. ENRIGHT: Maybe, Beth, do you want to come up
- 20 to the -- thanks.
- MS. BURROWS: I hope my questions will not be part
- of my presentation timing, however.
- MS. CRAGHEAD: No.
- 24 MS. BURROWS: In several places, you mentioned --
- 25 you said such things as many members felt ill-equipped,

- 1 members called upon the body for clarification and so forth.
- 2 How does one find out which members called for this?
- 3 MR. GREIFER: I'm not sure that the FAO record
- 4 from the meeting in '99 -- in October '99 would have
- 5 captured all the members. The -- I was part of the team
- 6 that was there. And some of the members that I recall from
- 7 my own personal memory is India was prominent. I think
- 8 Thailand may have been part of that group that also
- 9 expressed, Bangladesh. And what was the -- and I think
- 10 there were two others. They may have been South American
- 11 countries.
- 12 MS. BURROWS: Thank you. I do have a copy. But I
- will hold off giving it to you so that you can pay wrapped
- 14 attention. My name is Beth Burrows, B-E-T-H B-U-R-R-O-W-S.
- 15 I am the president and director of a small public interest
- 16 group named the Edmonds Institute. I speak today, however,
- on behalf of the following organizations: My own, the
- 18 Edmonds Institute, the Sierra Club, Pesticide Action Network
- 19 of North America, the International Center for Technology
- 20 Assessment, the Center for Food Safety, the Council for
- 21 Responsible Genetics, ACERCA, the Campaign to Label
- 22 Genetically-engineered Foods, Ground Score, Fish Berries,
- 23 Washington Biotechnology Action Council, the 49th Parallel
- 24 Biotechnology Consortium, Mothers for Natural Law, and the
- 25 Institute for Social Ecology.

1	I left my office a day ago. There might have been
2	others who asked me to be added to this list. I apologize
3	to them if I have missed their names.
4	I want to thank you for the opportunity to present

our views here today. Collectively, the civil society organizations whose names I have mentioned have carefully followed the process leading up to the finalization of the Cartagena protocol on biosafety.

After many years of deliberation, the Cartagena biosafety protocol was deemed by many, many nations the principal international instrument for the regulation of trans-boundary movements of LMOs. The protocol has been signed by over 60 countries to date with governmental deliberations and ratifications proceeding at a pace to ensure that the protocol enters into force by the next conference of the parties to the convention on biological diversity in April 2002.

International meetings have already been held and are scheduled to be held to ensure the protocol's timely implementation. The United States was present at all such meetings. And its representatives on many occasions professed a willingness to comply with the spirit of the protocol. Hence, it is with some surprise that we note the efforts by our own government to side-step the international commitments outlined in the protocol by rushing to create a

- 1 shadow set of standards in the IPPC.
- 2 The IPPC is not the appropriate forum to deal with
- 3 the risks of genetically-engineered plants unless it is the
- 4 intention of the United States to quarantine all LMOs at the
- 5 border. The international community was absolutely clear
- 6 about what was the proper venue for risk assessment during
- 7 the negotiations that led to the Cartagena biosafety
- 8 protocol.
- 9 Negotiators considered this exact question and
- 10 agreed that IPPC was not adequate to regulate trans-boundary
- 11 movements of LMOs. To create at this point some of the same
- 12 procedures within the IPPC as may fall under the scope of
- the protocol would be to create international confusion,
- 14 potential further delay in the establishment of appropriate
- 15 rules for the shipment of genetically-engineered organisms
- and an unnecessarily duplicative, regulatory bureaucracy
- with all the extra cost, red tape, personnel training and
- overlapping mandates that such a move ensures.
- 19 Moreover, the creation of such a bureaucracy would
- 20 multiply the amount and duration of rancor in the
- 21 international arena over the products of genetic
- 22 engineering. We think the administration must know that
- 23 such political maneuvering will be seen as a cynical United
- 24 States attempt to gain control of an arena in which the
- 25 risks of genetic engineering are likely to be judged less

- 1 carefully than under the protocol.
- 2 It would also be seen as an extremely transparent
- 3 move by the U.S. to co-opt the judgement of the majority of
- 4 countries in the world. Such perception would only heighten
- 5 the already prevalent suspicion that we are a country that
- 6 is desperate to force our products onto global markets no
- 7 matter the cost to capacity-building, democracy, safety or
- 8 mutual respect among nations.
- 9 This is clearly undesirable and an unnecessary
- 10 waste of money and good will for all concerned, most
- 11 certainly for the U.S. taxpayer and the U.S. farmer. We
- 12 strongly urge USDA APHIS and this administration to
- 13 recommend that IPPC consider the Cartagena biosafety
- 14 protocol as the proper venue for addressing all matters
- 15 related to the trans-boundary movement of LMOs.
- And that statement is signed by a variety of
- people representing the organizations that I mentioned
- 18 earlier. I won't read their names. I do have a few copies
- 19 of that statement. Thank you.
- MS. CRAGHEAD: Thank you very much for your
- 21 comments.
- 22 DR. ENRIGHT: Sure. If I can clarify about some
- 23 of the remarks that I made that may speak to you some of the
- 24 remarks that you made, just for clarity's sake. We have had
- 25 this discussion in the U.S., the potential for overlap with

- 1 regard to the scope of the CBD and the scope of the IPPC.
- 2 This discussion came after the October 1999 meeting at the
- 3 IPPC and it also followed the decision to establish a
- 4 working group to develop recommendations.
- 5 And our view is that it is not an either-or
- 6 situation and that the activities that may be sought or
- 7 developed under each of the organizations are not at odds
- 8 with one another. There are common areas of interest
- 9 between the CBD and the IPPC. But there are distinctions in
- 10 focus and there are distinctions in mechanisms available.
- 11 Under their -- under the IPPC, the effort will
- 12 focus due to its mandate specifically on the protection of
- plant health, life and resources, primarily we would
- 14 understand through the development of specific risk
- 15 assessment and management criteria. We are not viewing the
- development of these standards to be a consent procedure,
- 17 but rather to employ the existing mechanisms within the IPPC
- 18 for assessment, management and prevention.
- 19 The members of the IPPC also recognize -- and this
- 20 was a sentiment common to developing countries -- that many
- of the activities related to LMOs and those related to
- 22 invasive species that are going on under the IPPC, the
- 23 implementation of those activities are going to fall in many
- 24 instances on the shoulders of the National Plant Protection
- 25 Organizations that are -- that exist under the IPPC. And

- 1 the officials in those National Plant Protection
- 2 Organizations from several countries have expressed
- 3 confusion as to how they are going to implement these
- 4 additional activities.
- 5 So we don't look at the activity under the IPPC as
- 6 an alternative to the activities that are under the CBD, but
- 7 look at it as a way to help those that are addressing plant
- 8 pest risks associated with LMOs, to help them to better
- 9 address those associated plant pest risks.
- 10 MS. BURROWS: I don't know if I can ask a question
- or not. I don't want to take any more time --
- MS. CRAGHEAD: I think that it is probably
- 13 appropriate for you to ask a question if you have one.
- 14 MS. BURROWS: You said those officials have
- 15 expressed confusion. I now speak for the Edmonds Institute.
- 16 My mandate for the other groups was fulfilled. You say
- 17 those officials have expressed confusion. One of our
- 18 confusions is that we are talking about different officials.
- 19 In the case of IPPC, it is our perception that the officials
- 20 addressed tend to be in the Department of Agriculture in
- 21 countries.
- The officials that we are concerned with in the
- 23 CBD tend to be in the Departments of Environment, variously
- 24 named around the world. Our concern is that we believe that
- 25 those who reside in Departments of Environment are more

- 1 competent to assess risks to just the very things that you
- 2 named, health, life and resources. And so I would not be
- 3 surprised if there was confusion among the ministers of
- 4 agriculture on risk assessment. But I would be if there was
- 5 among the ministers of environment.
- 6 And I would hope that the United States is not
- 7 going to set up -- or help to set up two competing systems
- 8 or if certainly not in the United States, but in other
- 9 places because this -- we are really talking about different
- 10 people. And many of those developing countries do not have
- 11 the money to set up two systems, let alone -- some of them
- don't have the money for one, as you know.
- MS. CRAGHEAD: Well, thank you again for your
- 14 comments. Our second registered speaker is Kirk Miller. Is
- 15 Mr. Miller here? Thanks.
- 16 MR. MILLER: Good morning, everyone. I have a few
- 17 copies here for the -- I can leave a statement to leave with
- 18 the secretary after the meeting.
- MS. CRAGHEAD: Okay.
- 20 MR. MILLER: I am commenting this morning on
- 21 behalf of the North American Export Grain Association which
- 22 is comprised of grain and oil seed exporters and interested
- 23 parties whose purpose is to promote and sustain the
- 24 development of commercial grain and oil seed exports in the
- 25 United States.

1	The organization was chartered in 1912 and
2	incorporated in 1920. NAEGA is a not-for-profit
3	organization. Its members are privately and publicly-owned
4	companies and cooperatives. And we appreciate the
5	opportunity to attend and participate in this meeting today
6	on the topic of living and modified organisms and invasive
7	species.
8	My name is W. Kirk Miller. And I am the Director
9	of International Programs and Regulatory Affairs for NAEGA.
LO	Now, my comments today are focused in three general areas.
L1	First of all, support for APHIS's historical role as a
L2	guardian against the invasion of adverse pests affecting
L3	both domesticated and wild flora and fauna and its more
L4	recently added role in regulating the development and
L5	commercialization of products derived from biotechnology;
L6	and secondly, support for the International Plant Protection
L7	Convention and the regional plant protection organizations,
L8	NAPPO in particular, and their involvement in setting
L9	standards and providing coordinated regulatory guidance on
20	living modified organisms and invasive species including the
21	LMOs.
22	And thirdly, and continued support for the WTO-SPS
23	agreement as a way to address sanitary and phyto-sanitary
24	matters including plant risk associated with LMOs and/or
25	products derived from biotechnology and quarantined pests

- 1 that are invasive.
- 2 Regarding support for APHIS's historical role,
- 3 APHIS is part of the network of federal agencies with food
- 4 safety responsibilities. APHIS's primary role in this
- 5 network is to protect U.S. agriculture from plant and animal
- 6 pests and diseases. The agency effectively implements
- 7 federal laws pertaining to animal and plant health,
- 8 international sanitary and phyto-sanitary regulations and
- 9 regulation of veterinary biological and vaccines, control
- 10 and eradication of introduced pests and diseases and humane
- 11 treatment of animals.
- 12 APHIS also conducts research and operational
- activities to reduce bird, rodent and predator damage to
- 14 crops and livestock. And APHIS programs are implemented
- through cooperative activities with other federal agencies,
- 16 state and foreign governments and producers. APHIS also
- 17 plays an important role in regulating biotechnology by
- 18 ensuring that bio-engineered plants do not harm the
- 19 environment.
- NAEGA believes that as a result of revisions to
- 21 the Plant Protection Act in 2000, APHIS has a clear mandate
- 22 to protect plant health and establish regulations related to
- 23 plant pest concerns that may be due to LMOs and/or products
- 24 that are brought in by biotechnology. If after further
- 25 review the agency finds that statutory authority is not

- 1 adequate to address the issues -- these issues, the agency
- 2 should work with stakeholders and Congress to amend the law.
- 3 The risk analysis and management systems currently used for
- 4 protecting agriculture are appropriate for assessing and
- 5 management threats to both wild flora and fauna posed by
- 6 biotechnology.
- 7 And regarding support for the International Plant
- 8 Protection Convention, the International Plant Protection
- 9 Convention is an international agreement that was
- 10 established in 1951 with the objective of helping to reduce
- 11 the spread of injurious plant pests and diseases worldwide.
- 12 The purpose of the convention is to secure a common and
- 13 effective action to prevent the spread and introduction of
- 14 pests of plants and plant products and to promote
- 15 appropriate measures for their control.
- The role of IPPC now includes establishing
- international phyto-sanitary standards, promoting the
- 18 harmonization of plant quarantine activities, facilitating
- 19 the dissemination of phyto-sanitary information and
- 20 providing plant health assistance to developing countries.
- 21 And recently, we think as a result of the adoption of the
- 22 Plant Protection Act and APHIS's involvement in that, we
- 23 also think by extension, the IPPC is now involved in
- 24 regulating LMOs.
- In the last round of more lateral trade talks, the

- 1 World Trade Organization recognized and established a
- 2 process to utilize the IPPC in addressing trade disputes
- 3 rooted in plant pest matters. The IPPC definition of a pest
- 4 is any species, strain or biotype of plant, animal or
- 5 pathogenic agent injurious to plant or -- plants or plant
- 6 products.
- 7 The coverage of the IPPC definition of plant pest
- 8 includes weeds and other species that have indirect effects
- 9 on plants. Therefore, the scope of the convention applies
- 10 to the protection of wild flora resulting in an important
- 11 contribution to the conservation of biological diversity.
- 12 The IPPC provides for rights and obligations supported by a
- 13 system of standards and procedures for identifying pests
- 14 that threaten plant health, assessing the risk and
- determining measures to be used to assess and manage those
- 16 risks.
- 17 The IPPC mandate to protect plant health is broad
- 18 enough to include plant pest concerns that may be presented
- 19 by LMOs and products of modern biotechnology. And the IPPC
- 20 risk analysis and management systems are appropriate and
- 21 relevant for assessing and managing risk to both cultivated
- and wild flora and plant products due to LMOs.
- 23 Under the IPPC network, national mechanisms and
- 24 institutional structures exist which form a basis for
- developing practical approaches in managing risk associated

1	with LMOs. NAEGA supports recommendations from the June
2	2000 working group of the Interim Commission on Phyto-
3	sanitary Measures regarding the development of supplementary
4	standards to specifically address phyto-sanitary measures
5	regarding LMOs and/or products of modern biotechnology.
6	APHIS through the IPPC and the North American
7	Plant Protection Organization should assert authority over
8	the regulation of invasive plant pests and/or those that may
9	be used as biological control agents. In this regard, APHIS
10	should take the lead in coordinating upcoming IPPC and NAPPO
11	decisions within the U.S. Government and undertake other
12	measures to engender public confidence in these actions.
13	Finally, in regard for support for the WTO-SPS
14	agreement, the WTO-SPS agreement contains many references to
15	risk assessment and the obligation of countries to base
16	their sanitary and phyto-sanitary measures on sound,
17	scientific risk assessments, evidence and principles. In
18	accordance with the SPS agreement, WTO members must also
19	take into account the objective of minimizing negative trade
20	effects when determining their appropriate level of
21	protection.

The same non-trade distorting concepts should apply to the U.S. regulation of LMOs and invasive species so that action on these matters provides appropriate protection, but not impose unjustified or unwarranted

- 1 barriers to commerce or invite retaliation against U.S.
- 2 exports.
- NAEGA encourages APHIS to coordinate its
- 4 activities in this regard with other branches of the U.S.
- 5 Government to enhance the agency's impact and results.
- 6 APHIS needs to address these issues in such a manner that
- 7 will engender public support and prevent unnecessary
- 8 barriers to domestic or international commerce.
- 9 NAEGA applauds APHIS for conducting this meeting.
- 10 And we look forward to working with the agency to address
- 11 these substantive matters. Thank you.
- 12 MS. CRAGHEAD: Thank you for your comments. The
- 13 third registered speaker is Gary Martin.
- 14 MR. MILLER: Gary is not going to be here today.
- 15 MS. CRAGHEAD: Gary is not here today? Great. We
- 16 will go on to Val Giddings who is not here, also. And
- 17 Matthew Lyons. Do you want to say anything?
- 18 MR. LYONS: Thank you. I have no prepared
- 19 remarks.
- MS. CRAGHEAD: Okay. On to number 6. Michael
- 21 Dobres? Am I saying that appropriately? Michael Dobres
- 22 with NovaFlora? No? All right. And our last registered
- 23 speaker is Charles Margulis.
- MS. REID: I am here on his behalf.
- 25 MS. CRAGHEAD: Okay. Great.

- 1 MS. REID: On behalf of Greenpeace USA, thank you
- 2 for the opportunity to present our views here today.
- 3 Greenpeace's supporters in the U.S. and abroad are devoted
- 4 to protecting the environment from threats to the
- 5 biodiversity -- to biodiversity.
- 6 MS. CRAGHEAD: May I interrupt you and ask you to
- 7 tell us who you are?
- 8 MS. REID: Oh, I'm sorry.
- 9 MS. CRAGHEAD: That's okay.
- 10 MS. REID: I am Kelly Reid. I also work for
- 11 Greenpeace.
- MS. CRAGHEAD: Sorry about that. Thanks.
- MS. REID: That's okay. This is my first time.
- MS. CRAGHEAD: Okay.
- 15 MS. REID: We have been involved as official
- 16 observers to the development and implementation of the
- 17 Cartagena protocol since the first discussions about an
- international instrument on biosafety took place in 1995 in
- 19 Madrid.
- The protocol is the culmination of many years of
- 21 hard work by diplomats and others around the world to
- 22 protect biodiversity from the threat of genetically-
- 23 engineered organisms referred to in the protocol and
- 24 hereafter as living modified organisms, or LMOs. We view
- 25 this current U.S. initiative to develop an alternative

- 1 standard-setting process on LMOs within the IPC with extreme
- 2 dismay.
- 3 This initiative threatens to negate the enormous
- 4 effort undertaken by the international community to finalize
- 5 the Cartagena protocol. The suggestion that the IPPC should
- 6 be the body to devise international rules and regulations on
- 7 the trans-boundary movement of LMOs was debated early on in
- 8 the negotiations of the Cartagena protocol.
- 9 Precisely because the IPPC is so narrow in scope
- and because the risks posed by LMOs go far beyond the
- definition of pest as defined in the IPPC, the countries
- 12 involved in the protocol negotiations explicitly decided
- that the convention was an inadequate forum for the broader
- 14 risks to the environment posed by LMOs.
- 15 The protocol was, thus, developed as a more
- 16 comprehensive regime for the regulation of LMOs. Thus, it
- seems odd and disingenuous for the U.S. to be considering
- 18 now a reversion to a less comprehensive treaty. We question
- 19 the need for the U.S. Government to invest time and energy
- 20 in such a task.
- 21 Already U.S. insensitivity to international
- 22 opinion on trade in genetically-engineered crops has bruised
- 23 relationships with trading partners and cost U.S. farmers
- 24 markets both to the east and to the west. To use another
- international instrument to force more unwanted products on

- 1 these and other countries would only exacerbate the current
- 2 conflicts.
- Indeed, at the last meeting of the
- 4 Intergovernmental Committee on the Cartagena protocol, the
- 5 E.U. and Norway already expressed concern about this
- 6 initiative within the IPPC and asked for a review of these
- 7 efforts at the next meeting of the Intergovernmental
- 8 Committee in October 2001. Given the strong statements made
- 9 by these countries that the IPPC was not the appropriate
- 10 forum for standards setting, it would seem prudent for the
- 11 U.S. to reconsider this initiative.
- 12 The U.S. should instead spend its diplomatic
- 13 efforts mending relationships bruised by its current and
- 14 political stance on LMOs rather than causing further damage
- 15 to our markets and our international trading relations.
- 16 That's it.
- 17 MS. CRAGHEAD: Thank you very much. That is the
- 18 end of my list of registered speakers. Is anyone else
- interested in speaking? Please come --
- MS. RISSLER: May I?
- MS. CRAGHEAD: Certainly.
- 22 MS. RISSLER: Thank you very much. I am Jane
- 23 Rissler, R-I-S-S-L-E-R, with the Union of Concerned
- 24 Scientists. UCS is a nonprofit, public interest group that
- 25 has been working in the area of biotechnology regulation for

- 1 some years. Our focus is primarily in the United States.
- I don't have a statement today. I am -- I want to
- 3 ask some questions because I am trying to understand what
- 4 this process is as far as the U.S. Government is concerned.
- 5 And so I would like to ask what -- was the U.S. -- I am
- following up on Ms. Burrows' question about the member
- 7 countries that asked for this investigation or this
- 8 clarification. Was the U.S. directly or indirectly
- 9 operating through other countries or one of the countries
- 10 requesting this IPPC involvement?
- MR. GREIFER: No.
- MS. RISSLER: So the U.S. has not played a
- 13 leadership role in having the IPPC be involved in the GMO
- 14 issue.
- 15 MR. GREIFER: We were very surprised by the
- statements made by a number of these developing countries in
- 17 this area. It was almost -- it took us by complete surprise
- 18 that there should be this call among some quarantine
- 19 officials from various countries asking for guidance in the
- 20 forum that they usually get for other plant quarantine pest
- 21 issues.
- 22 And so the -- I guess in their minds that the
- 23 procedures and the quidance that is available through IPPC
- 24 for pest risk analysis, that the question in their minds was
- is there adequate -- are these adequate procedures for

- 1 evaluating the phyto-sanitary aspects of both GMO products
- 2 and evasive. So I can categorically and unambiguously tell
- 3 you that there was no effort on our part to influence their
- 4 raising those questions and concerns.
- 5 MS. RISSLER: Does the U.S. now see this as an
- 6 opportunity to undermine the biosafety protocol?
- 7 DR. ENRIGHT: I will answer that.
- 8 MS. RISSLER: Okay.
- 9 DR. ENRIGHT: No. That is not the -- that is not
- 10 the impetus here. The impetus here is a recognition that
- 11 even though many ministries of environment are working on
- these issues outside of the IPPC, the responsibility to
- implement these activities is going to fall on the National
- 14 Plant Protection Organizations in many of these countries,
- 15 particularly in the western hemisphere.
- So it is my understanding that the request for
- 17 further guidance was concomitant with that recognition. And
- 18 the guidance is in order to -- the guidance that they are
- 19 requesting is to be able to specifically address the plant
- 20 pest risk concerns that may be associated with LMOs or
- 21 invasive species in regards to plant health, to actually be
- 22 able to provide in a standard specific assessment criteria
- 23 so that these countries, these National Plant Protection
- Organization officials when making these decisions whether
- 25 they do so in order to implement the IPPC or in order to

- 1 implement activities external to the IPPC, it is so that
- 2 they make better informed phyto-sanitary decisions.
- 3 MS. RISSLER: I noted -- thank you. I noted that
- 4 your role, Dr. Enright, is coordinating among U.S. agencies.
- 5 I am trying to understand what agencies are involved and
- 6 what this coordination is and from whence cometh the impetus
- 7 to take this on as a seemingly important APHIS initiative.
- 8 DR. ENRIGHT: Do you want me to address the first
- 9 --
- 10 MS. RISSLER: Yes, first. What is being -- who is
- 11 being coordinated? What agencies are being coordinated in
- 12 this effort?
- 13 DR. ENRIGHT: I can address that. That is one of
- 14 my roles here in APHIS. It is USDA, Department of Commerce,
- 15 Customs, Interior, FDA, EPA, USTR -- have I left anyone out
- 16 -- State Department, of course. I am trying to think if I
- 17 have left anyone out.
- 18 MR. GREIFER: Within the Department, of course,
- 19 the Forest Service --
- 20 DR. ENRIGHT: Right. Fish and Wildlife from
- 21 Interior.
- MS. RISSLER: So this is a big deal.
- 23 MR. GREIFER: Invasive Species Council.
- DR. ENRIGHT: It is a big deal because it is my
- 25 way of operating to have the process be inclusive rather

- 1 than to be exclusive. I would rather have criticism at the
- 2 beginning. I would rather be able to craft a position and a
- 3 direction that all of the agencies can agree with. I just -
- 4 it is my personal way of operating and I think it makes
- for good governance.
- 6 MS. RISSLER: And to whom do you report on this?
- 7 DR. ENRIGHT: I report to John Greifer. I report
- 8 to my boss, Dr. Ellen Green, to John Payne here in
- 9 Riverdale.
- 10 MS. RISSLER: All right. This is helpful. I am
- just trying to understand how important this is and how big
- an effort it is going to be and how threatening it is going
- 13 to be.
- 14 MR. GREIFER: Can I add one thing about the -- and
- 15 it goes back to a question asked earlier about the need out
- 16 there that has been expressed. That the working group that
- met in June of last year was a rather large -- it was an
- 18 open-ended working group. And it was a rather large number
- 19 -- you know, more -- 35 countries' governments showed up.
- 20 And it is a lot larger than most types of working groups of
- 21 that sort.
- 22 And the working group report, which I hope you
- 23 have a copy of, is basically a consensus report. There
- 24 wasn't in it anyone dissenting from considering that within
- 25 the scope of the IPPC, that anything that could harbor a

- 1 pest of quarantine concern, that anything, anything whether
- 2 it is a truck, whether it is a conventional plant or
- 3 commodity, food commodity or whether it is a GMO/LMO
- 4 product, it should -- it would be a dereliction of duty and
- 5 responsibility by the IPPC to be not looking at anything
- 6 that could present a phyto-sanitary risk.
- 7 And it was in that context that countries decided
- 8 that at a minimum, they need to explore this. As a result,
- 9 the group of 35 countries met in June and agreed that, in
- 10 fact, there is some responsibility, some role here to look
- 11 at -- to develop. So if you do not have a copy of the
- 12 report --
- MS. CRAGHEAD: There is one on the registration
- 14 table.
- 15 MS. RISSLER: You do hear -- you do hear the
- 16 concern though about the threat to the biosafety concern.
- 17 You do hear that at this meeting, that there is concern
- about threats to the biosafety protocol.
- 19 MR. GREIFER: Absolutely, loud and clear.
- 20 MS. CRAGHEAD: Thanks very much for your questions
- 21 and comments.
- MS. RISSLER: Thank you.
- MS. CRAGHEAD: One more?
- MS. BURROWS: I think I have a big voice. There
- is no need for me to get in front of the room. Just a

- 1 clarification again. I am impressed by the fact that the
- 2 United States so quickly responded to a call for help on
- 3 looking at specific risks engendered by LMOs. And your
- 4 comment by this help was not forthcoming in terms of funds
- 5 for capacity-building within the biosafety protocol or maybe
- 6 this is the beginning of that.
- 7 MS. CRAGHEAD: I'm not sure that is in the scope
- 8 of the meeting. Is it?
- 9 DR. ENRIGHT: Oh, I can answer that.
- 10 MS. CRAGHEAD: Okay.
- DR. ENRIGHT: Sure. I will answer that, Beth,
- based on my experience with the biosafety protocol. The
- language that is in the article on capacity-building in the
- 14 biosafety protocol is much narrower than U.S. proposed
- 15 language. And we were surprised at how other countries
- 16 disapproved the willingness to support capacity-building
- 17 within the text of the protocol.
- 18 That said, in the protocol's implementation, I
- 19 think that the U.S. has been extremely proactive in helping
- 20 to get the implementation stage activities off the ground.
- MS. BURROWS: Do you include generosity in the
- 22 phrase proactive?
- 23 DR. ENRIGHT: State Department says I can say
- 24 generosity, yes. Yes.
- MS. BURROWS: I would be interested in the figures

- because I really feel I --
- DR. ENRIGHT: I will turn to Dr. Paul Pfeiffer
- 3 from the State Department's Bureau of Oceans, Environment
- 4 and Science for that.
- DR. PFEIFFER: Thanks, Cathy. Paul Pfeiffer with
- 6 the State Department.
- 7 DR. ENRIGHT: Oh, Paul, can you -- thanks.
- 8 DR. PFEIFFER: Sorry. Hi. I am Paul Pfeiffer
- 9 with the Department of State. I am the working level lead
- on the biosafety protocol since Cathy has been gone and
- 11 moved over to USDA. I am not sure what you consider
- generous, Beth. But we are actually working with the
- 13 Commission on Biological Diversity. We are giving them
- about \$360,000.00 to implement the biosafety clearinghouse
- which is the information database.
- It is sort of the backbone I think of the
- information sharing that the protocol is going to entail.
- 18 The country is going to put up their domestic regs., their
- 19 domestically -- their final decisions on product approvals
- 20 back home. And it is also a way that is going to facilitate
- 21 this advance informed agreement sharing of information.
- 22 So -- and we have been also trying to play helpful
- 23 roles at the -- it was the first IPPC meeting which is the
- 24 Intergovernmental Committee for the Cartagena protocol. We
- 25 went there and participated in -- as a full government. And

- 1 I am assuming that it wasn't as productive on capacity-
- 2 building as I had hoped actually. That during that full
- 3 week, what they decided to do was to hold two more meetings
- 4 which are going to be held this June in Cuba. And plans are
- 5 for the U.S. Government to participate in those, as well.
- 6 MS. BURROWS: Fine. I will be interested to know
- 7 the budget for capacity-building in IPPC vis-a-vis risk
- 8 assessment of genetically-modified organisms. I -- just for
- 9 the record, \$360,000.00 for a biosafety clearinghouse from
- 10 the single largest nation doing genetic engineering in the
- 11 world does not seem generous.
- DR. PFEIFFER: It is a -- they estimate it will
- 13 cost about \$500,000.00. And I think the U.K. has actually
- 14 given up some to it already. So hopefully we will get there
- in the next year. There is a pilot phase that --
- 16 MS. BURROWS: A clearinghouse isn't the only --
- DR. PFEIFFER: Right.
- 18 MS. BURROWS: -- thing necessary for capacity-
- 19 building.
- 20 DR. PFEIFFER: Yes. And what we have been trying
- 21 to do is work with the developing countries. And this is
- 22 what we tried to do in France. Was to get them to come to
- 23 us and say, okay, these are our capacity-building
- 24 priorities. Unfortunately, as I said, in France, we didn't
- 25 get there.

- 1 Hopefully, after June, we will get there. And
- then there is going to be an IPPC-II meeting in October in
- 3 Montreal. Basically, the developed country approach. Both
- 4 the E.U. and U.S. has kind of been, okay, we need you to set
- 5 the priorities as the developing countries and then we will
- 6 come back and work with you. So we have really been
- 7 hesitant to come out and say this is the capacity-building
- 8 that needs to be done.
- 9 MS. CRAGHEAD: Thanks very much. I appreciate
- 10 that. Is -- does anyone else want to speak today? I have a
- 11 gentleman in the back. Hi. Come on up, please.
- 12 MR. POWELL: I wanted to make a brief comment in
- 13 response to --
- 14 MS. CRAGHEAD: Will you tell us who you are?
- 15 Thanks.
- 16 MR. POWELL: My name is Mark Powell. I am with
- 17 the USDA Office of Chief Economists in the Office of Risk
- 18 Assessment and Cost Benefit Analysis. And I just wanted to
- 19 make a brief comment as a point of clarification for
- 20 participants today that may not be familiar with -- that may
- 21 be more familiar with other domestic agencies.
- 22 And that is that the role that Cathy is playing
- 23 and that APHIS is playing in this process is not unique to
- 24 the IPPC. There are other offices within USDA and other
- 25 domestic agencies that are charged with coordinating U.S.

- 1 policy on international matters.
- 2 For example, the Kodex Alimentarius Secretariat is
- 3 housed in USDA's Food Safety and Inspection Service. But
- 4 its responsibility, its charge is for coordinating U.S.
- 5 policy on food safety matters across agencies. And so I
- 6 just wanted to put to rest any notion for those that might
- 7 be unfamiliar with those sorts of processes that this is not
- 8 novel or unique to this instance. Thank you.
- 9 MS. CRAGHEAD: Thanks very much for your comment.
- 10 MS. NATSOULAS: I just have a question.
- 11 MS. CRAGHEAD: Will you tell us who you are?
- 12 MS. NATSOULAS: My name is Andrianna Natsoulas and
- 13 I am with Greenpeace. Thanks.
- MS. CRAGHEAD: Thank you.
- 15 MS. NATSOULAS: I have two questions,
- 16 clarifications. My name is Andrianna Natsoulas and I am a
- 17 contractor with Greenpeace. I have heard the list of
- 18 agencies that you named who are involved. I am wondering
- 19 two things. One, will genetically-engineered fish standards
- 20 be included in this program that you are working on now?
- 21 And secondly, will you also be addressing evasive species
- 22 associated with imports of seafood products, for example,
- 23 shrimp and the white spot virus?
- 24 MR. GREIFER: The scope of the convention is
- limited to plant health. And so things that may present

- 1 either an impact on animal health or human health are
- 2 outside the scope of the convention. But if it is a -- some
- 3 kind of organism, whether it is -- that travels via water
- 4 that can be shown to have an impact on plant health, then it
- 5 would presumably be within the scope.
- 6 MS. NATSOULAS: Okay. So, for example, the white
- 7 spot virus, the FDA has found that it does survive within
- 8 the water that the shrimp are frozen in and then imported
- 9 into the U.S. And the virus itself has been found to be
- 10 alive in the water. So if that water goes into the ground
- and affects plant life through ground water, would that be
- included in these standards?
- 13 MR. GREIFER: That would -- well, the standards
- 14 are going to be more process-oriented. They will not be
- 15 specific. But the -- presumably, if it can be demonstrated
- 16 that there is something that would harm plant health in some
- 17 way, then it would come within the scope.
- 18 MS. NATSOULAS: So there is a possibility.
- 19 MR. GREIFER: Yes. And so it would just be the --
- 20 it would be then the basis for being able to demonstrate
- 21 that it would be the basis for being able to adopt a phyto-
- 22 sanitary response -- a phyto-sanitary measure to respond to
- 23 it. But we -- I think it is really important that people
- 24 understand that the IPPC is really limited to plant health.
- 25 Animal health is -- would be -- animal health issues and

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standards would be covered by the Office of International
1
 2
      Zootics.
 3
                MS. NATSOULAS:
                                 Okay.
 4
                MR. GREIFER: And food safety, of course, is
5
      Kodex.
6
                MS. NATSOULAS:
                                 Thank you.
 7
                MS. CRAGHEAD: Thanks very much for your question.
      Anyone else? No one? Well, thanks a lot for coming today.
8
9
      We appreciated all of your comments and your interest in
10
      this. And the meeting is adjourned. Have a good afternoon.
11
                (Whereupon, at 11:05 a.m. on Thursday, March 8,
12
      2001, the hearing in the above-entitled matter was
      adjourned.)
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LMOs and Invasive Species, Public Meeting

Name of Hearing or Event

Riverdale, Maryland

Place of Hearing

March 8, 2001

Date of Hearing

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